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IN THE UNITED STATES PATENT AND TRADEMARK OFFICE
BEFORE THE BOARD OF PATENT APPEALS AND INTERFERENCES

IN RE: BATES, et al.)
) APPEAL NO. _____
SERIAL NO: 09/879,710)
)
FOR: S-METHYL-CYSTEINE, S-ETHYL-) REPLY BRIEF
CYSTEINE, AND RELATED)
S-ALKYLTHIOLS AS ANTAGONISTS)
TO THE EFFECTS OF S-)
NITROSOTHIOLS AND NITRIC OXIDE))
)
FILED: June 12, 2001)
)
GROUP ART UNIT: 1655)

To the Commissioner of Patents and Trademarks
P. O. Box 1450
Alexandria, VA 22313-1450

Dear Sirs:

Appellants respectfully request that the following Reply Brief be entered into the record. It addresses new arguments set forth in the Examiner's Answer.

CERTIFICATE OF MAILING BY EXPRESS MAIL

I hereby certify that this document and the documents referred to as enclosed therein are being deposited with the U. S. Postal Service in an envelope as "Express Mail Post Office to Addressee" addressed to: Commissioner of Patents, P. O. Box 1450, Alexandria, VA 22313-1450, prior to 5:00 p.m. on 18th day of August, 2005.

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I. Introduction

The arguments made in the Examiner's answer are based on unsupported theories and assumptions, without basis in established patent law, the references of record, record on appeal, or in the claims themselves. The rejections are therefore entirely meritless and should be reversed.

II. Anticipation Rejection

Claims 2, 3, 8, and 10 were rejected under 35 U.S.C. 102(b) as being anticipated by Meisner.

The Examiner first states that, "Appellants argue that Meisner teaches a method which uses a composition which contains four substances, namely ascorbic acid, a precursor or stimulant of epinephrine or nor-epinephrine production such as tyrosine or phenylalanine (amino acids of which S-methyl cysteine is also an amino acid), calcium and a mild anti-inflammatory substance which can be methylycysteine." (Examiner's Answer, bottom of p. 5 to top of p. 6). Apparently, the Examiner is attempting to argue (without explicitly saying so) that since tyrosine and phenylalanine are amino acids, as is methylycysteine, they are the equivalent of methylycysteine. This, of course, is ridiculous, since it is well known in the art that the various amino acids are not structurally or functionally equivalent, as acknowledged by Meisner, which lists tyrosine and phenylalanine in one category of compounds (i.e. stimulants of epinephrine or nor-epinephrine production) while listing methylycysteine in another category (i.e. an anti-inflammatory substance).

The Examiner again completely discounts the "consisting essentially of" language of independent claim 10, stating that such language can simply be ignored on the basis that,

"Appellants never explained on the record how their method's composition did not contain elements which materially changed the fundamental characteristics of the invention only that Meisner contained other elements and therefore their claims were excluded by "consisting essentially of". (Examiner's Answer, p. 6, first full paragraph). The Examiner then states that, "Appellant was reminded that unless they can show that the additional elements in Meisner materially changed the fundamental characteristics of their invention then the composition of Meisner and that of the claims was one and the same..." (Examiner's Answer, p. 6).

It is the Examiner that apparently needs reminding that the record, namely the specification, does provide an explanation of elements that would materially change the fundamental characteristics of the invention, as already noted by Appellants. In this regard, the specification explicitly states that:

Current treatment options for hypotension or shock from such conditions such as septic shock, toxic shock syndrome, spinal cord injury, effects of anesthetics, and anaphylaxis, etc. are limited to vasoconstricting agents that may have deleterious side effects that limit their effective therapeutic usage.

(Spec. p. 2, second paragraph). Thus, Appellants have already noted on the record that vasoconstricting agents are unsuitable for use in its treatment methods, and therefore outside of the scope of claim 10 and claims 2-8 depending therefrom.

Meisner, of course, requires the presence of a vasoconstricting agent (Col. 2, lines 67-68 to Col. 3, lines 1-6), namely a precursor or stimulant of epinephrine or nor-epinephrine production, in its method. Since Appellants' claimed invention does not include a vasoconstricting agent, Meisner does not read on claims 2-8 and 10. The claimed invention is therefore not anticipated by Meisner.

The Examiner's next states that Appellants' argument that Meisner requires the presence of a vasoconstrictor is without merit, because Meisner does not directly teach the use of the vasoconstricting agents epinephrine and nor-epinephrine, but precursors of the same. Appellants fail to see the distinction. Meisner notes that tyrosine and phenylalanine are precursors or stimulants of epinephrine or nor-epinephrine production. (Col. 3, lines 1-3). Whether the compounds disclosed by Meisner directly provide vasoconstriction, form compounds that are direct vasoconstrictors, or stimulate vasoconstrictor production, the end result is the same.

III. Obviousness

In attempting to refute Appellants' arguments pertaining to the obviousness rejection, the Examiner attempts to argue yet again that Meisner does not teach the use of a vasoconstricting agent since tyrosine and phenylalanine are merely precursors of vasoconstricting agents, and not actually vasoconstrictors themselves. Again, the Examiner is attempting to make a distinction where one simply does not exist.

In the next part of the Brief, the Examiner states that, "these vasoconstricting agents [tyrosine and phenylalanine] could be amino acids which S-methylcysteine is." (Examiner's Brief, p. 7, second paragraph). Thus, in this statement, after extensively trying to argue that precursors of vasoconstricting agents are not vasoconstrictors, the Examiner admits that tyrosine and phenylalanine are vasoconstrictors. However, now the Examiner has returned to the previous argument that all amino acids are the same. Again, Meisner herself would disagree that the vasoconstricting agents tyrosine and phenylalanine can be exchanged for the anti-inflammatory amino acid S-methylcysteine, or vice versa. (See e.g. Col. 4, lines 33-61). The Examiner's argument is analogous to stating that Vitamin C and Vitamin K are

interchangeable since they are both vitamins, even though their functions are very different, i.e. Vitamin C is an antioxidant while Vitamin K is essential for normal blood clotting.

Finally, the Examiner states that, "the claims never require the patient to suffer from anything, thus the argument that the invention is aimed at avoiding the side effects of vasoconstrictors is without merit since anyone according to the claims can be administered this composition claimed no matter what their need is." (Examiner's Answer, p. 7, second full paragraph). While difficult to understand exactly what the Examiner is attempting to argue here, it seems that the Examiner is requiring Appellants' claims to specifically state that the method is used to "avoid the side effects of vasoconstrictors." Such a limitation would be redundant and pointless since the intended use or purpose of the compound described in the specification is cited for interpreting the scope of the "consisting essentially of" transition phrase in claim 1. Again, a cited objective of the invention is to avoid the side effects of vasoconstrictors, thereby precluding the use of such compounds in Appellants' claimed method since such compounds would "materially affect the basic and novel characteristic(s) of the claimed invention." MPEP § 2111.03.

The Board and the Federal Circuit have routinely construed the meaning of "consisting essentially of" in claims based on statements made by the applicant in the specification. See, e.g., PPG Industries v. Guardian Industries, 156 F.3d 1351, 1355, 48 USPQ2d 1351, 1355 (Fed. Cir. 1998) ("PPG could have defined the scope of the phrase 'consisting essentially of' for purposes of its patent by making clear in its specification what it regarded as constituting a material change in the basic and novel characteristics of the invention."). See also AK Steel Corp. v. Sollac, 344 F.3d 1234, 1240-41, 68 USPQ2d 1280, 1283-84 (Fed. Cir. 2003) (Applicant's statement in the specification that "silicon contents in the coating metal should not exceed about 0.5% by weight" along with a discussion of the

deleterious effects of silicon provided basis to conclude that silicon in excess of 0.5% by weight would materially alter the basic and novel properties of the invention. Thus, "consisting essentially of" as recited in the preamble was interpreted to permit no more than 0.5% by weight of silicon in the aluminum coating.). The same type of evaluation should apply here as well.

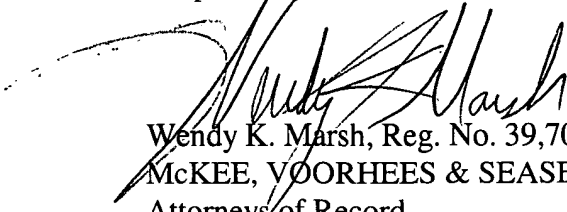
Since Meisner does not teach or suggest the use of a composition that does not include a vasoconstricting agents, claims 2-8 and 10 are not rendered obvious by Meisner. The rejection of claims 2-8 and 10 under 35 U.S.C. § 103 should therefore be reversed.

IV. Conclusion

Therefore, for the above-stated reasons, and for the reasons set forth in Appellants' appeal brief, Appellants respectfully request reversal of the decision of the Examiner, and allowance of the application.

It is not believed a fee is due with this brief. If a fee is due, please consider this a request to debit or credit Deposit Account No. 26-0084 accordingly.

Respectfully submitted,



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